UNITED STATES PATENT APPLICATION

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FOR: COLLECTION ASSEMBLY

RELATED APPLICATIONS

This application claims priority on U.S. Provisional Patent Appl. No. 60/405,048, filed on August 20, 2002 and is a continuation-in-part of pending U.S. Patent Appl. No. 09/933,653 and U.S. Patent Appl. No. 10/114,542.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The invention relates to collection containers, such as collection containers used for collecting specimens of bodily fluid.

2. Description of the Related Art

[0002] Tubes are used to collect specimens or samples of bodily fluid. The typical tube includes a cylindrical sidewall with a spherically generated closed bottom and an open top. A closure is mounted to the open top to permit sealing of the tube. The closure typically comprises an elastomeric stopper that is urged into the open top of the tube. The closure also may include a rigid plastic member that retains the elastomeric stopper. The plastic member can be used to manipulate the stopper for placing the closure in the open top of the tube or for removing the closure from the tube. The elastomeric stopper may be formed from a pierceable and resealable

material. Some closures also include a layer of foil across the top of the closure for enhanced performance of the closure as a gas or moisture barrier. Tubes typically are formed from either glass or plastic. Glass tubes perform well as gas and moisture barriers, but are more fragile than plastic tubes. Hence, glass tubes may require special handling. Plastic tubes are substantially unbreakable. However, certain plastics may be permeable to gases or moisture.

[0003] A sample of fluid collected in a tube typically is sent to a laboratory for analysis. Characteristics of the collected sample may change if the sample is exposed to ambient gases or if vapors produced by the sample are permitted to permeate through the walls of the tube and into the ambient surroundings. Characteristics of the collected sample also may vary after exposure to gas trapped between the surface of the collected fluid sample and the stopper. The volume between the top of the collected sample and the stopper is referred to herein as the head space.

[0004] Most laboratory analysis of collected fluid samples are performed with automated or semi-automated equipment. The equipment typically is geared to accommodate tubes of specified outside dimensions. Tubes that are too small may require separate handling, and hence tubes with non-standard outside dimensions may require slower less efficient and more costly analysis of the specimens collected therein. Accordingly, most health care facilities collect specimens in standard sized tubes. However, some tests can be performed with relatively small volumes of a fluid sample. A collection of a small volume sample in a relatively large tube necessarily creates a large head space with a large volume of air above the collected sample. Accordingly, there is a greater probability that characteristics of a small collected sample will vary prior to testing due to interaction or reaction with the relatively large volume of air in the head space.

[0005] It is desirable to provide a tube with standard outside dimensions. It is also desirable to collect only the smallest volume of a sample that is required for a particular laboratory analysis. Furthermore, it is desirable to provide a smaller and substantially uniform head space.

SUMMARY OF THE INVENTION

[0006] The subject invention is directed to sample collection containers. The sample collection containers have selected outside dimensions to conform with instruments and equipment employed in a laboratory. The sample containers, however, have wall dimensions selected to achieve a small and uniform head space between the top of the collected sample and the bottom of the closure.

[0007] The container may be a tube with a substantially cylindrical outer surface. The bottom of the tube may be closed and may have a substantially spherically generated outer surface. The top of the tube is open.

[0008] The walls of the container may be of different thicknesses at various locations between the closed bottom of the container and the open top. For example, walls of the container adjacent the open top may have a thickness selected in accordance with strength requirements of the container and/or in accordance with standard dimensions for the closure. The walls of the container spaced from the open top, however, may have a thickness greater than the thickness of the container at the open top. The greater thickness of the container walls at locations spaced from the open top function to reduce the volume of the space in the container. Thus, a small volume of a fluid sample can be collected without significantly increasing the head space and achieving a desirably low sample to head space volume ratio.

[0009] The collection container may be formed from a plastic material by a molding process, such as co-injection, two-shot molding or other known process to provide an integral or unitary matrix of plastic between inner and outer surfaces of the container. Alternatively, the collection container may comprise a plurality of nested containers. The nested containers may comprise an outer container of substantially uniform wall thickness and an inner container with a variable wall thickness. The inner container can be slidably inserted into the outer container so that the two containers function as a single container assembly. The variable thickness of the inner container may comprise a thin wall portion adjacent the open top of the inner container and a thick wall portion adjacent the bottom of the inner container. The thickness of the thick wall

section of the inner container is selected to achieve a small head space that can be uniform for a range of collected specimens of a particular type and a particular volume. The thin wall section of the inner container may be dimensioned for engagement by at least part of the closure.

[0010] The outer surface of the inner container and/or the inner surface of the outer container may be formed with surface configurations to facilitate nesting of the two containers. The surface configurations can include a roughening along at least a portion of the outer surface of the inner container or the inner surface of the outer container. The roughening defines an array of peaks and valleys, and air that would otherwise be trapped between the containers can escape through the valleys as the containers are being assembled. Hence, an air lock is not likely to be created as the inner and outer containers are assembled. Furthermore, compressed air will not exist in the minute spaces defined between the inner and outer containers, and accordingly migration of air through the inner wall of the inner container is substantially reduced or eliminated.

[0011] The invention also is directed to a system of containers. All of the containers in the system have uniform outside shapes and dimensions. However, the wall thicknesses of the containers vary among groups of containers within the system. As a result, the volume of fluid that can be collected by the containers in the system varies among at least certain of the containers. The volume is inversely related to the thickness of the walls of the containers. All of the containers within the system, however, provide a substantially uniform head space.

DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 is a side elevational view of a tubular container in accordance with the subject invention.

[0013] FIG. 2 is a perspective view of the container shown in FIG. 1.

[0014] FIG. 3 is a top plan view of the container show in FIGS. 1 and 2.

[0015] FIG. 4 is a cross-sectional view taken along line 4-4 in FIG. 3.

[0016] FIG. 5 is a longitudinal cross-sectional view of a second embodiment of a container assembly in accordance with the subject invention.

[0017] FIG. 6 is an exploded perspective view of the container of FIG. 5.

[0018] FIG. 7 is a longitudinal cross-sectional view of a third embodiment of a container assembly in accordance with the subject invention.

[0019] FIG. 8 is a longitudinal cross-sectional view of a fourth embodiment of a container assembly in accordance with the subject invention.

[0020] FIG. 9 is a longitudinal cross-sectional view of a fifth embodiment of a container assembly in accordance with the subject invention.

[0021] FIG. 10 is a longitudinal cross-sectional view of a sixth embodiment of a container assembly in accordance with the invention.

DETAILED DESCRIPTION

[0022] A container in accordance with the subject invention is identified generally by the numeral **10** in FIGS. 1-4. Container **10** includes a generally tubular sidewall **12**, a closed bottom **14** and an open top **16**. Tubular sidewall **12** includes a cylindrically generated outer surface **18** defining a diameter "a" as shown in FIG. 1. Closed bottom **14** of container **10** has a substantially spherically generated outer surface **20** characterized by a concave dimple **22** centrally disposed on the closed bottom.

[0023] Tubular sidewall **12** of container **10** is further characterized by an inner surface **24** of substantially stepped cylindrical configuration. In particular, inner surface **24** includes a cross-sectionally small section **26** adjacent bottom end **14** of container **10** and a cross-sectionally large section **28** adjacent open top **16**. Cross-sectionally small section **26** has an inside diameter "b" as shown in FIG. 4, while cross-sectionally large section **28** has an inside diameter "c". Inside diameter "c" at cross-sectionally large section **28** is dimensioned to achieve tight engagement with a closure (not shown in FIGS. 1-4). Container **10** is molded unitarily from a plastic material by a molding process.

[0024] The stepped inside surface **24** of container **10** enables a small volume of fluid to be collected without altering outside dimensions of container **10**. Thus, outside diameter "a" enables container **10** to be used with standardized laboratory equipment. However, the stepped cylindrical inner surface **24** enables a small volume of fluid to be collected in container **10** without an undesirably large head space.

[0025] Container **10** may have a sidewall **12** and a bottom wall **14** with thicknesses dimensioned to achieve a volume ranging from about 1 mL to about 4 mL. Fluid samples of these volumes are acceptable for many testing procedures and enable a head space in the range of 5-16 mm (i.e., 0.8-1.5 mL) to be achieved. Tubes of similar construction but with different wall thicknesses and different inside diameters for inner surface **24** can be used to achieve different fluid volumes without significantly affecting the head space. Container **10** can be used with a closure, such as an elastomeric stopper inserted into open top **16**. The stopper may function to maintain a vacuum in container **10** so that container **10** can be used for drawing a sample of blood.

[0026] The embodiment of the invention depicted in FIGS. 1-4 shows tube **10** formed from plastic material by a co-injection process or other molding process familiar to those in the art. For example, an outer portion of tube **10** may be molded from a first plastic and an inner portion may be molded from a second plastic. The co-injection or other molding process achieves an integral or unitary matrix of plastic between inner and outer surfaces **24** and **18**. The plastics selected for the inner and outer portions of tube **10** are selected in accordance with specific requirements, such as compatibility with the stored material, liquid impermeability, gas impermeability and such. FIGS. 5-8 show an alternate embodiment where tube assemblies comprise inner and outer tubes. In particular, FIGS. 5 and 6 show a tube assembly **40** with an outer container **42** and an inner container **44**. Outer container **42** includes a substantially cylindrical tubular sidewall **46**, a closed bottom **48** and an open top **50**. Tubular sidewall **46** includes a cylindrically generated outer surface **52** and a cylindrically generated inner surface **54**. Outer surface **52** and inner surface **54** of outer tube **42** are of substantially uniform cross-section along the entire length of tubular sidewall **46**. Thus, tubular sidewall **46** is of substantially uniform thickness along its length.

[0027] Inner tube **44** includes a tubular sidewall **56**, a closed bottom **58** and an open top **60**. Tubular sidewall **56** has an outer surface **62** and an opposed inner surface **64**. A roughened region that defines an array of peaks and valleys extends along at least a portion of the outer surface **62**, as shown most clearly in FIG. 6. The diameter defined by the peaks on outer surface **62** of tubular sidewall **56** substantially equals the inside diameter of inner surface **54** on sidewall **46** of outer tube **42**. The valleys between the peaks on the roughened outer surface **62** define an outside diameter that is less than the inside diameter of inner surface **54** of sidewall **46** on outer tube **42**. The valleys on roughened outer surface **62** define circuitous or tortuous paths that permit an escape of air **A** as inner tube **44** is being inserted into outer tube **42**. Thus, assembly of tubes **42** and **44** is easier and there is no build-up of high pressure air between inner and outer tubes **42** and **44**.

[0028] Inner surface **64** of inner tube **44** has a substantially cylindrical portion **66** extending up from closed bottom **58** and an outwardly tapered portion **68** adjacent open top **60**. Cylindrical portion **66** of inner surface **64** defines an inside diameter "d". Inside diameter "d" is selected to achieve a preferred volume for tube assembly **40**. In the illustrated example of FIG. 5, tube assembly **40** accommodates 3.5 ml.

[0029] Tube assembly **40** is employed with a closure **70** to seal inner tube **44** and outer tube **42** adjacent the respective open tops **60** and **50**, and in some embodiments to maintain a low pressure. Thus, a selected volume of blood can be collected in tube assembly **40** by placing the evacuated interior of tube assembly **40** in communication with a blood vessel. This communication can be achieved with a conventional needle holder, a blood collection set or other known means. In the illustrated example, closure enables the 3.5 mL fluid sample to be collected, while retaining a head space of approximately 5-16 mm (i.e., 0.8-1.5 mL).

[0030] FIG. 7 illustrates a tube assembly **80** that is similar to tube assembly **40**. In particular, tube assembly **80** includes an outer tube **42** identical to outer tube **42** described above with respect to FIG. 5. Tube assembly **80** further includes an inner tube **84** that is similar to inner tube **44** of tube assembly **40**. In particular, inner tube **84** has a tubular sidewall **86**, a closed bottom **88** and an open top **90**. Tubular sidewall **86** has an outer surface **92** that may be substantially identical to the outer surface **62** of inner tube **40**. Inner tube **84** further includes an

inner surface **94** with a cylindrically generated section **96** adjacent closed bottom **84** and an outwardly tapered section **98** adjacent open top **90**. Cylindrically generated section **96** of inner surface **94** defines an inside diameter "e" that is less than inside diameter "d" of cylindrical portion **66** on inner surface **64** of inner tube **44**. As a result, tube assembly **70** can accommodate a volume of about 3.0 mL while achieving a head space of 5-16 mm (i.e., 0.8-1.5 mL) substantially equal to the head space achieved with tube assembly **40**.

[0031] FIG. 8 shows a tube assembly **100** with an outer tube **42** substantially identical to outer tube **42** of tube assemblies **40** and **80**. Tube assembly **100** also includes an inner tube **104** that has a tubular sidewall **106**, a closed bottom **108** and an open top **110**. Tubular sidewall **106** has an outer surface **112** that may be substantially identical to outer surface **62** of sidewall **56** on inner tube **44**. Tubular sidewall **106** further has an inner surface **114** with a cylindrically generated section **116** adjacent closed bottom **108** and an outwardly flared section **118** adjacent open top **110**. Cylindrically generated section **116** of inner surface **114** defines an inside diameter "f" that is less than inside diameter "e" of inner tube **84**. As a result, tube assembly **100** can accommodate a fluid sample of only about 2.0 ml, while achieving a head space of 5-16 mm (i.e., 8-1.5 mL) substantially equal to the head spaces of the tube assemblies **40** and **80**.

[0032] The system of tubes depicted in FIGS. 5-8 enables collection of a fluid sample of appropriate size for a particular laboratory test to be performed, but without affecting the head space.

[0033] The reduced volume and substantially uniform head space can be achieved by providing an effectively thicker bottom wall as shown in FIG. 9 instead of or in addition to the variable thickness of the sidewalls. In particular, FIG. 9 shows a tube assembly **120** with an outer tube **42** substantially identical to the outer tube **42** shown in FIGS. 5-8. Additionally, tube assembly **120** includes a closure **70** that may be substantially identical to the closures shown in FIGS. 5-8. Tube assembly **120** further includes an inner tube **124** with a projection **126** at the closed bottom end thereof. As a result, a raised bottom wall **128** is spaced considerably above closed bottom **48** of outer tube **42**. Accordingly, inner tube **124** defines a smaller volume than inner tube **44** in the embodiment of FIGS. 5 and 6 without an increase in wall thickness. Furthermore, the projection **126** enables the closed bottom of inner tube **124** to be raised without

a significant increase in thickness of inner tube **124**. In this latter regard, a significantly increased thickness at the bottom of inner tube **124** could complicate molding.

[0034] The container of the subject invention may include closures that extend greater distances into the container for reducing the head space and achieving a substantially uniform head space for different volumes of fluid. In particular, FIG. 10 shows a container assembly **130** with an outer tube **42** substantially identical to the outer tube of the embodiments shown in FIGS. 5-9. Assembly **130** further includes an inner tube **134** that is very similar to inner tube **44** in the embodiment of FIGS. 5 and 6. However, inner tube **134** is shorter than inner tube **44**. Tube assembly **130** further includes a closure **170** that is similar to closure **70** on the embodiments of FIGS. 5-9. However, closure **170** includes an internal section **172** with a length "h" that exceeds the corresponding length of closure **70** shown in the embodiments of FIGS. 5-9. The greater length "h" compensates for the shorter length of inner tube **134** and effectively reduces both the volume of tube assembly **134** and the head space. The different length closures **170** can be used with or instead of the different effective thicknesses for the bottom wall (FIG. 9) and/or the different thicknesses for the sidewalls (FIGS. 5-8).